DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Fujisawa USA, Inc., to American Pharmaceutical Partners, Inc.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Fujisawa USA, Inc., Deerfield, IL 60015–2548, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA 100–840 (Chorionic Gonadotropin) to American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160. Accordingly, the agency is amending the regulations in 21 CFR 510.600 and 522.1081 to reflect the transfer of ownership. The agency is also amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by removing Fujisawa USA, Inc., because the firm is no longer the sponsor of any approved NADA's, and by alphabetically adding a new listing for American Pharmaceuticals Partners, Inc.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Fujisawa USA, Inc.,'' and by alphabetically adding an entry for ''American Pharmaceutical Partners, Inc.,'' and in the table in paragraph (c)(2) by removing the entry for ''000469'' and by numerically adding an entry for ''063323'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * *	* * *
American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160	063323
* * * *	* * *

(2) * * *

Drug labeler code	Firm name and address
* * * *	* * *
063323	American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160
* * * *	* * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1081 [Amended]

4. Section 522.1081 *Chorionic gonadotropin for injection; chorionic gonadotropin suspension* is amended in paragraph (a)(2)(ii) by removing ''Nos. 000469 and 058639'' and adding in its place ''Nos. 058639 and 063323''.

Dated: Aug 27, 1998
August 27, 1998

Margaret Ann Miller

Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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